



A systematic review of the current status of interventions for type II endoleak after EVAR for abdominal aortic aneurysms

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ABSTRACT

Objective: To study the mid- and long-term outcomes of type II endoleak treatment after EVAR and the technical aspects of different techniques to exclude endoleaks which different embolic agents.

Methods: A systematic review was performed using the approach recommended by the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines for meta-analyses of interventional studies. The comprehensive search was conducted using the following database: MEDLINE, EMBASE, and the Cochrane Library. Patient characteristic, intervention approaches, embolic agents, and results at mid and long term follow up were studied.

Results: A total of 6 studies corresponding to a total of 141 patients fulfilled the inclusion criteria with a mean age of 73–78.6 years and a mean duration of follow up varying from 25 to 42 months. There were different techniques for embolization used (translumbar, transarterial, and transcaval approach) with various types of embolic agents. In all studies, the indication for embolization of the type II endoleaks was sac enlargement of more than 5 mm. A wide range of technical success rate was reported regardless of the intervention strategy being used (17,6%–100%). The overall technical success rate of all studies was 62%.

Conclusion: This systematic review shows that there is a wide variety of techniques to exclude a persistent type II endoleak. Different kinds of embolic agents have been used. Due to a lack of peer reviewed data on longterm follow-up, it was not possible to come to recommendations what treatment would be the best for a durable exclusion of a persistent type II endoleak after an initially successful EVAR. There remains an urgent need for proper executed studies, either randomized or with close observation in relation to longer follow-up.

1. Introduction

Endovascular aneurysm repair (EVAR) is the most widely used treatment procedure for an infrarenal abdominal aortic aneurysm (AAA) for both elective repair and a ruptured case. The success rate at short term follow-up after EVAR is higher than that of open AAA repair [1–3]. The most common complication after EVAR is endoleak [3–5].

Type II endoleak does not usually require immediate treatment, it is the most common type of endoleaks with an occurrence rate of 20–30% [6,7]. Type II endoleak occurs from retrograde collateral blood flow into the aneurysm sac, such as from the inferior mesenteric, lumbar, sacral, and/or hypogastric arteries [8,9].

The criteria for intervention vary across the literature. The major indication has been a persistent type II endoleak and/or an associated sac expansion > 5 mm. [5,10,11]. Several Endovascular treatment of type II endoleaks involves embolization, endoscopic ligation, aneurysm sac plication and surgical explants [12–18]. The most favorable embolization approach are transarterial and translumbar/direct sac puncture.

Although type II endoleaks are treated for several decades by embolization of the collateral arteries responsible, it is still not clear which endovascular technique and with what embolic agent may result in the best durable solution. So far, no systematic review has focused on the mid and long term outcome.

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2. Methods

2.1. Search strategy and study selection

We conducted a systematic review using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines for meta-analyses of interventional studies and the AMSTAR (Assessing the methodological quality of systematic reviews) guidelines [42]. The following databases were used: MEDLINE, EMBASE and the Cochrane Library.

The following keywords and any combination of them were used in our search strings: 'Blood Vessel Prosthesis Implantation' OR 'Aortic Aneurysm', 'Abdominal' AND 'Endovascular Procedures' OR 'evar' OR 'endovascular aneurysm repair' AND 'Postoperative Hemorrhage' OR 'endoleak' OR 'postoperative hemorrh' OR 'Perigraft Leak' OR 'sac enlargem' AND 'type II' OR 'type 2' OR 'T2EL' OR 'ELII' OR 'TII EL'. In the Cochrane database the publications were searched manually.

The search started in February 2019 in English and was limited to clinical human adult studies. To update the results, the search was identically repeated in January 2020. We also included guidelines and review-articles. The references cited in published original articles were searched to identify additional articles.

The first two authors (MMA and DRP) independently screened all titles and abstracts identified in the search to include reports on type II endoleak after EVAR. Then full-text studies were reviewed independently with differences resolved by consensus. All articles of relevant studies were retrieved and further examined in detail. Inclusion criteria were (1) clinical research studies, (2) patients after EVAR with a mean follow up after embolization of 24 months or more, (3) conservative treatment received by patients, (4) reintervention using endovascular technologies, or surgical ligation or conversion to open repair. Exclusion criteria were (1) case report studies, (2) included additional types of endoleaks, (3) duplicated data, (4) languages other than English.

2.2. Data extraction and quality assessment

Data extraction was performed by two authors (MMA and DRP) independently and any conflict was resolved by consensus (MMA, FLM and JVH). Extracted data included type of study, number of patients with type II endoleaks, criteria for endovascular intervention routes (transarterial, translumbar, direct puncture sac, and transcaval), type of embolic agents (ethylene vinyl alcohol copolymer, coils, glue, lipiodol, thrombin, or vascular plug), technical success rate, follow-up duration after reintervention, re-endoleak incident, persistent sac enlargement, aneurysm rupture, and other complications.

The assessment of methodological quality of the selected studies was carried out by MMA and DRP using the Modified Coleman Methodology Score (CMS). The score has been widely used in systematic reviews for analyzing outcomes of surgical and conservative treatment options, particularly in orthopedic studies, and has a maximum score of 100. A score of 100 indicates that the study has largely avoided chances of various biases and confounding factors. For our systematic review, the score was adjusted so that it was more relevant to assess the methodological quality of studies on type II endoleak treatment after EVAR. Each study was scored from 0 to 90 based on 9 of the following aspects: (1) study size, (2) mean follow up, (3) surgical approach, (4) type of study, (5) description of diagnosis, (6) description of surgical technique, (7) outcome criteria, (8) procedure of assessing outcome, and (9) description of subject selection process. We excluded the aspect of post-operative rehabilitation and therefore, the maximum score was 90 [19,20]. (see Supplemental Table I)

Heterogeneity of the studies did not allow for meta-analysis.

3. Results

Out of 3399 identified studies, we retrieved 2280 potentially

relevant articles which were assessed further for eligibility. In total, there were only 6 articles that met all the inclusion criteria. The flow chart of study identification and selection is given in Fig. 1. Study characteristics of the included studies are summarized in Table 1 and Table 2; while Table 3 lists methodological quality of the included study of this systematic review. All included studies showed low scores of the Modified Coleman Methodology Score ranging from 29 to 38 of the maximum score of 90.

Overall, included studies corresponded to a total of 141 patients with a range age of 73–78.6 years and a range duration of follow up from 25 to 42 months. All studies used identical indication for reintervention, which was sac enlargement of more than 5 mm (Table 2). There were different types of reintervention treatment (translumbar, transarterial, and transcaval) using various types of embolic agents (Table 2).

71 Patients underwent transarterial embolization approach. 41 patients underwent direct aneurysm sac puncturing. 55 patients used embolant Coil + Onyx, glue, and Onyx and 28 patients used only coil (Table 2). Eleven patients who underwent transarterial embolization approach with onyx had a success rate of 54,5% (Table 2).

We only found one article about transcaval embolization approach that stands the inclusion criteria. 26 patients who underwent transcaval embolization approach using onyx had a success rate of 100% (Table 2).

A wide range of technical success rate was reported regardless of the intervention type used in those studies (17,6%–100%). The overall technical success rate of all studies was 62%. The success rate of first re-intervention treatment after EVAR with transarterial, translumbar, and direct puncture approach using onyx and onyx + coil was better compared to the approach using only coils. The most commonly found among the participants was secondary re-endoleak (15,3% to 70,5%), which was followed by persistent sac enlargement in 3,8% to 82,35%.

Intervention after secondary endoleak was rarely reported and was only mentioned in two studies. Three patients underwent open repair after first re-intervention, in which they were subsequently treated with laparotomy, ligation of lumbar vessels, sac exploration, and sac plication around the endograft.

4. Discussion

Type II endoleak is most commonly found complication among all types of endoleaks after EVAR, with a reported incidence of 34% (18% self-limiting early type 2 endoleak, 5% persistent type 2 endoleak, and 11% new onset type 2 endoleak during follow up) [5,21–24]. Almost half of patients with endoleaks have persistent or late endoleaks with sac enlargement described by van Marrewijk et al. with a reported re-intervention rate of 50% in 2 years [11]. It usually requires reintervention treatment including embolization [21]. Although many types of reintervention techniques are performed for decades, little has been known on its mid and long term outcomes, and no conclusion on the best treatment option is available.

Unfortunately, in this systematic review only a limited number of relevant studies with only midterm follow-up was found. All studies exhibited low score of methodological quality based on the Modified Coleman Methodology Score ranging from 29 to 38 from a maximum score of 90. The low score was acquired due to small number of patients, limited period of follow up, and the retrospective design of all studies. Moreover, different procedures were described without any selective differentiation in the results.

The included studies reported a mean age ranging from 73 to 78.6 years. Guo Q et al. suggest that older age is a risk factor for the onset of type II endoleaks and that it favors high-pressure aneurysm sacs. Other factors include patent inferior mesenteric artery (IMA) and patent lumbar arteries [25].

In this study age is the only risk factor that could be assessed. Patent IMA and patent lumbar arteries were not reported as preoperative risk factors during midterm follow-up.

The best way to treat a type II endoleak is still debated and there are

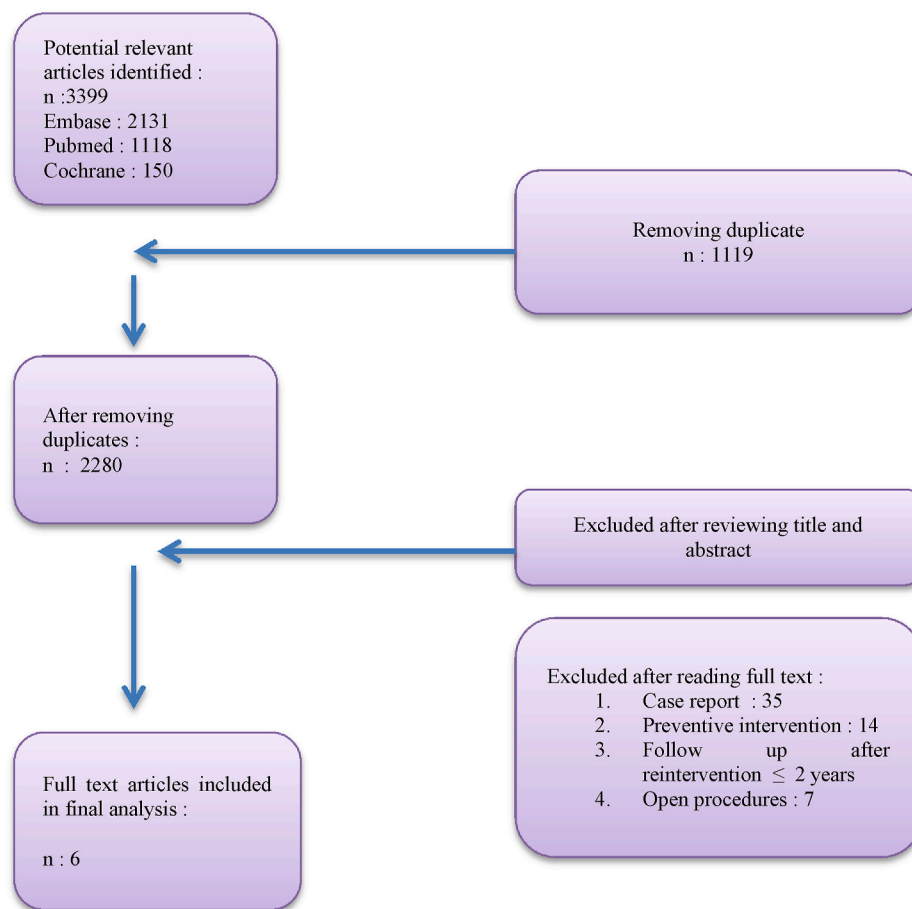


Fig. 1. PRISMA flow chart for the review.

Table 1
Characteristics of the studies.

Author	Year	Numbers of patient (pts)	Type of Study	Mean follow up After EVAR (mo)	Mean Age (years)	Criteria of treatment	Mean follow up After Reintervention (mo)	Type of Reintervention
S.Rahimi et al. [39]	2018	29	Cohort	>6	78,8 (69–91)	Sac enlargement >5 mm	38,4	Transarterial embolization Translumbar embolization
R.Gandini et al. [30]	2014	26	Cohort	6	73 (68–78)	Sac enlargement >5 mm	25,9	Selective Transcaval embolization Non-selective Transcaval embolization
M.S Khaja et al. [34]	2014	16	Cohort	30	79 (69–92)	Sac enlargement >5 mm	32,8	Transarterial embolization
R.Muller et al. [35]	2012	11	Cohort	20,5	68 (37–83)	Sac enlargement >5 mm	26	Transarterial embolization
Ikram-Ul Haq et al. [41]	2017	28	Cohort	1	76 (67,3–84,7)	Sac enlargement >5 mm	37	Transarterial embolization Translumbar embolization
K.A Gallagher et al. [40]	2012	29	Cohort	Unknown	78,6 (54–87)	Sac enlargement >5 mm	42	Transarterial embolization

varied results of short term clinical outcomes in published literature [26, 27]. The treatment of type II endoleaks can be performed via a transarterial approach or direct translumbar endoleak puncture [28,31–33]. From each of these approaches there are advantages and disadvantages that must be considered such as the length of the procedure, the positioning during the procedure, and the possibility of post operative infection. Described technical success of the procedure included complete embolization of the endoleaks including the endoleaks-causing

branch vessels, complete embolization of the endoleaks nidus with partial embolization of the branch vessels, and complete embolization of the endoleaks until branch vessels were no longer visualized [29]. Unfortunately, the best reintervention treatment for patients with type II endoleaks could not be determined as there was lacking selective information regarding the different outcomes of different used techniques. In this study, a high success rate was found for transcaval approach (100%) [30]. Transcaval embolization was performed in 12 patients

Table 2
Characteristics of technical intervention.

Author	Mean follow-up after reintervention (mo)	Number of patients (pts)	Embolitic agent	Intervention type	Result (pts)										
					Technical success (n, %)	Re-endoleak	Persistent sac enlargement	Rupture	Open repair	Laparoscopic clipping	Ligation lumbal	Technical failure	Unknown	Secondary Intervention	
S.Rahimi et al. [39]	38,4	29	Coil + Onyx	17 Direct sac puncture/ Translumbal 10 Transarterial	14 (48,2%)	13 (44,8%)	8 (27,5%)	2	6						10
R.Gandini et al. [30]	25,9	26	Coils, Acrylic glue mix lipiodol, Trombin	9 Non selective transcaval 17 selective transcaval	9 (100%)	4 (15,3%)	1 (3,8%)	1	1						4
M.S Khaja et al. [34]	32,8	18	9 Onyx 7 (Coils, NBCA, Amplatzer)	13 Direct sac puncture 5 Transarterial	11(84,6%) 5 (100%)	9 (50%)	5 (27,7%)				1	2			7
R.Muller et al. [35]	26	11	Onyx	10 Transarterial	6 (54,5%)	3 (27,2%)	3 (27,2%)		1	1					3
Ikram-Ul Haq et al. [41]	37	28	Coils	17 Transarterial	5 (29,4%)	12 (70,5%)	10 (58,8%)							3	
K.A Gallagher et al. [40]	42	29	Coils, Onyx	11 Translumbal 28 Transarterial,	3 (27,3%) 8/11 (72,7%)	7(63,6%)	8 (72,7%) 3(27,2%)			1				1	2
					3/17 (17,6%)		14 (82,3%)		2					1	10

Table 3
Modified coleman methodology score.

Criteria	Author					
	S.Rahimi et al. [39]	R.Gandini et al. [30]	M.S Khaja et al. [34]	R.Muller et al. [35]	Ikram-UI Haq et al. [41]	K.A Gallagher et al. [40]
Part A (only one score to be given for each section)						
Studi size: number of patients	4	4	0	0	4	4
Mean follow-up, months	5	5	5	5	5	5
No, of different treatment procedures included in each reported outcome. More than 1 method may be assessed, but separate outcomes should be reported	0	7	0	10	0	0
Type of study	0	0	0	0	0	0
Diagnostic certainly	5	5	5	5	5	5
Description of treatment given	3	5	3	5	3	3
Part B (Scores could be given for each option in each of the 3 section)						
Outcome criteria	3	3	3	3	3	3
Procedure for assessing outcome	4	4	4	4	4	4
Description of subject selection process	5	5	5	5	5	5
Total score	29	38	25	37	29	29

with technical success rate of 92%. One year after transcaval embolization, type II endoleak was not found in 10 of 11 patients and the diameter of aneurysm sac was reduced, clinical success was obtained 83%. This study was confirmed by the results reported by Mansueto et al. They concluded that transcaval embolization is a feasible technique for the complete exclusion of type II endoleaks [13]. They also reported a lack of data because of the small sample sizes and the fact that all articles in their review were retrospective observational studies that caused bias.

In our calculation regarding the application of embolic agents, one study used onyx with technical success rate of 54,5%, another study used coils with technical success rate of (27,3%-29,4%), whereas technical success rate in other studies could not be determined because they used a number of different embolic agents [30,34,35,39–41]. Onyx has good initial clinical results with complete occlusion of nidus in two studies [34,35]. A successful translumbar embolization with onyx is also possible, as described by Martin et al. [36] Ribe et al. reported study type II endoleak treatment with intra-arterial approach with onyx. The result showed it was safe and effective over a follow up of 19 months [37].

Baum and Stavropoulos reported an experience with the combination of coils and glue for treatment of type II endoleaks. They demonstrated a significant increased failure rate with the transarterial (80%) versus translumbar (8%) approach with mean follow up of 13,2 and 8,5 months [28,38]. Despite these nice studies, it is impossible to determine which approach and/or embolic agent is the best because the mid and long term follow-up is poorly done.

Treatments of type II endoleak with relatively short-term follow up have reasonably good results, but there are only 6 studies with a proper mean follow up of more than 2 years and that re-endoleak was the most common reported, followed by sac enlargement (52%) and even a rupture of the aneurysm sac described by van Marrewijk et al. (2004) [11]. These findings are consistent with the general notion that the occurrence of re-endoleak and sac enlargement are still high [30,34,35, 39–41]. Open procedure can be an option to treat re-endoleak, but in some cases it is not possible to be performed due to the anatomical abnormalities, so laparoscopic clipping could take the place of it.

4.1. Limitations

Our study is limited by lack of type II endoleak articles with long term follow-up which lead to limited number of sample and data heterogeneity. Furthermore, the data taken from most of the research used in our inclusion criteria were retrospective. Samples in term of the number of embolic agents used towards intervention type are unspecified (Table 2).

5. Conclusion

In general, in type II endoleak patients with midterm follow-up in, the recurrence rate of an initially successful type II endoleak treatment is very high (65,4%).

This systematic review shows that there is still a lack of information about the best treatment to exclude persistent type II endoleaks after EVAR.

Transcaval procedures might be a promising technique for type II endoleaks. But the durability of the exclusion of the type II endoleaks at longer follow-up was poorly reported.

Due to such shortcomings, our search did not reveal whether the other embolization techniques by translumbar or transarterial approach are inferior or not. Open surgical or laparoscopic procedures might be a durable solution, but the few studies published are hampered by a small number of patients and lack of proper executed longer follow-up.

Based on the current peer reviewed articles, national and international guidelines are unable to recommend a best treatment choice. The individual physician's experience and access to the latest endovascular tools will determine which technique will be exercised.

There is an urgent need for proper executed studies, either randomized or with close observation and longer follow-up after exclusion of the persistent type II endoleaks and to prevent the aneurysm sac from growing after an initial successful EVAR procedure.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijssu.2021.106138>.

Data statement

International Journal of Surgery Author Disclosure Form.

The following additional information is required for submission. Please note that failure to respond to these questions/statements will mean your submission will be returned. If you have nothing to declare in any of these categories, then this should be stated.

Please state any conflicts of interest

No conflicts of interest.

Please state any sources of funding for your research

No funding

Please state whether ethical approval was given, by whom and the relevant Judgement's reference number

No ethical approval.

Research registration Unique Identifying number (UIN)

The World Medical Association's Declaration of Helsinki 2013 states in article 35: 'Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject'. Editors of IJS require that all types of research studies involving human participants should be registered prospectively and failing that retrospectively. There are many places to register your research, and you can choose which is the most suitable for your needs:

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Author contribution

Please specify the contribution of each author to the paper, e.g. study design, data collections, data analysis, Others, who have contributed in other ways should be listed as contributors. **M.M.Akmal:** Methodology, Validation, Software, Formal Analysis, Investigation, Writing-original draft; **D.R.Pabittei:** Validation, Investigation, Formal analysis, Writing-review & editing; **T.Prapassaro:** Investigation, Formal analysis, Writing-review & editing; **R.Suhartono:** Writing-review & editing; **F.L.Moll:** Conceptualization, Methodology, Supervision, Writing-review & editing; **J.A.van Herwaarden:** Conceptualization, Methodology, Supervision, Writing-review & editing.

Guarantor

The Guarantor is the one or more people who accept full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish. Please note that providing a guarantor is compulsory.

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